UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 01-CV-12257-PBS Subcategory Case. No. 06-11337
THIS DOCUMENT RELATES TO: *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.* Civil Action No. 05-11084-PBS	Hon. Patti B. Saris Magistrate Judge Marianne B. Bowler

CONCISE STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF DEY, INC., DEY, L.P., AND DEY L.P., INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey") submit this concise statement of the material facts of record as to which there is no genuine issue to be tried in support of its motion for partial summary judgment.

I. DEY'S BUSINESS

A. DEY'S HISTORY

1. Dey, Inc. is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive in Napa, California. Dey, Inc. is the general partner of Dey, L.P. which is engaged in the "development, manufacturing and marketing of prescription drugs used to treat selected respiratory diseases and allergies." (Affidavit of Pamela R. Marrs, dated June 25, 2009 ("Marrs Aff."), ¶ 4.)

2. Dey was founded in 1978 by four entrepreneurs as a small, start-up company selling generic respiratory medications. (Marrs Aff. ¶ 5.)

3. Dey's first products were unit-dose sodium chloride solution inhalation solutions ("saline solutions") which the company began to sell in 1978. Dey continues to sell all

of these products presently. (Marrs Aff. ¶ 6; Declaration of Sarah L. Reid, dated June 26, 2009 ("Reid Decl."), Ex. 1.)

4. From 1978 until the late 1980s, Dey's sales, marketing, and distribution facilities were in Texas and its manufacturing plant was in Concord, California. (Marrs Aff. ¶ 7).

5. During this time period, Dey principally sold saline solutions and other generic respiratory medications in unit dose vials, including acetylcysteine, introduced in 1986, and metaproterenol, introduced in 1987. (Marrs Aff. ¶ 8; Reid Decl., Ex. 1.)

6. In its first decade, Dey's principal customers were hospitals. (Marrs Aff. ¶ 9.)

7. In the late 1980s, Dey acquired a site in Napa, California. (Marrs Aff. ¶ 10.)

8. In 1989, Dey moved its manufacturing, sales, and marketing functions to the Napa site, but kept its distribution operations in Texas. (Marrs Aff. ¶ 11.)

Dey's Albuterol

9. Once Dey moved its manufacturing facilities to Napa and received FDA approval, it then had the capacity to manufacture albuterol sulfate in unit dose vials. (Marrs Aff. ¶ 12.)

10. Albuterol sulfate ("albuterol") is a respiratory inhalation drug that is used for the relief of bronchospasm in patients with reversible obstructive airway disease and acute attacks of bronchospasm. (Marrs Aff. ¶ 13; Reid Decl., Ex. 2; Reid Decl., Ex. 3.)

11. Dey's principal generic albuterol product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment. (Marrs Aff. ¶ 14.)

12. Dey submitted an abbreviated new drug application ("ANDA") for albuterol unit dose in the later 1980s. (Marrs Aff. ¶ 15.)

13. Dey's application was approved in 1992 and in March 1992, Dey became the first pharmaceutical manufacturer to launch a generic albuterol unit dose solution and was the only generic manufacturer in the market for over one year after launch. (Marrs Aff. ¶ 16; Reid Decl., Ex. 4; Reid Decl., Ex. 5, at 169:14-20.)

14. Not only was Dey's albuterol product the first generic unit dose albuterol to market, it was the first BAC-preservative-free albuterol unit dose solution on the market. (Marrs Aff. ¶ 17; Reid Decl., Ex. 1.)

15. Dey became known and respected for the following breakthrough features of its products:

- The replacement of screwtop bottles with the first plastic unit-dose vials;
- Patient-friendly TwistFlex™ vials to reduce cross-contamination;
- BAC-preservative-free.

(Marrs Aff. ¶ 18.)

16. With the launch of albuterol, Dey began breaking into other markets, including homecare and to a lesser extent, retail. (Marrs Aff. ¶ 19.)

17. Dey did not have a large retail presence, in part, because it did not have a full line of albuterol products available for sale as other larger manufacturers did. (Marrs Aff. ¶ 20.)

18. Accordingly, Dey's retail sales for albuterol accounted for a small percentage of sales in the first few years after albuterol launched. (Marrs Aff. ¶ 21.)

19. Dey still manufactures and sells unit dose albuterol although it is not profitable. Currently, there are six other companies that market generic versions of albuterol. (Marrs Aff. ¶ 22; *see also* Reid Decl., Ex. 6.)

20. In the mid-1990s, Dey tried to expand its albuterol line of products so that it could compete better with the larger manufacturers. (Marrs Aff. ¶ 23.)

21. Dey therefore launched its multi dose albuterol product in March 1996 and its metered dose inhaler albuterol product in November 1996. (Marrs Aff. ¶ 24; Reid Decl., Ex. 5, at 176:3-177:14, 177:15-178:17.)

22. Dey did not manufacture either of these products, but purchased them from other manufacturers. (Marrs Aff. ¶ 25.)

23. When Dey entered the multi dose albuterol market, there were already a number of competitors selling the same product. (Marrs Aff. ¶ 26.)

24. Dey stopped selling multi dose albuterol in mid-2003. (Marrs Aff. ¶ 27.)

25. When Dey entered the metered dose inhaler market, there were already a number of competitors selling the same product. (Marrs Aff. ¶ 28.)

26. Dey stopped selling metered dose inhaler in early 2003. (Marrs Aff. ¶ 29.)

Dey's Cromolyn

27. In addition to albuterol, Dey was also pursuing opportunities to launch other generic respiratory inhalation solutions in the late 1980s and early 1990s. (Marrs Aff. ¶ 30.)

28. Dey thus submitted an ANDA for cromolyn sodium, which was the next generic inhalation solution coming off patent. (Marrs Aff. ¶ 31.)

29. Cromolyn sodium ("cromolyn") is a prophylactic respiratory inhalation drug used to treat patients with bronchial asthma. Dey's generic cromolyn product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment. (Marrs Aff. ¶ 32; Reid Decl., Ex. 7.)

30. Dey launched its cromolyn product in May 1994. (Marrs Aff. ¶ 33; Reid Decl., Ex. 5, at 170:4-171:14.)

31. As with unit dose albuterol, Dey was the first generic cromolyn on the market. (Marrs Aff. ¶ 33.)

32. Dey stopped manufacturing cromolyn in February 2008 as it was unable to sustain a profit on sales. (Marrs Aff. ¶ 35.)

33. Currently, there are at least seven companies that sell generic versions of cromolyn. (Marrs Aff. ¶ 34; Reid Decl., Ex. 8.)

Dey's Ipratropium

34. Ipratropium bromide ("ipratropium") is a respiratory inhalation drug used for the maintenance treatment of bronchospasms associated with Chronic Obstructive Pulmonary

Disease ("COPD"), which is a term used to describe a number of airway diseases, including both chronic bronchitis and emphysema. (Marrs Aff. ¶ 37; Reid Decl., Ex. 9.)

35. Ipratropium is classified as an anticholinergic bronchodilator because it works by preventing the bronchial smooth muscle from constricting. (Marrs Aff. ¶ 37; Reid Decl., Ex. 10.)

36. In January 1997, Dey launched a sterile generic unit dose ipratropium bromide solution. (Marrs Aff. ¶ 36; Reid Decl., Ex. 5, at 174:13-175:11; Reid Decl., Ex. 11.)

37. Dey's generic ipratropium product is a unit dose liquid solution that is administered via a nebulizer, which is a piece of durable medial equipment. (Marrs Aff. ¶ 38.)

38. Dey continues to sell ipratropium at a close to break even profit level. (Marrs Aff. ¶ 39.)

39. Currently, there are at least seven other companies that sell generic versions of ipratropium. (Marrs Aff. ¶ 39; Reid Decl., Ex. 12.)

Further Evolution of Dey's Business

40. By the late 1990s, with increased competition in the generic markets for albuterol, cromolyn, and ipratropium and the quickly eroding profit margins on those drugs as well as the limited number of respiratory drugs delivered via nebulization coming off patent in future years, Dey decided to switch its business model to focusing on developing, manufacturing and selling branded inhalation solutions. (Marrs Aff. ¶ 40.)

41. Dey launched two branded inhalation solutions, AccuNeb and DuoNeb, in 2001. (Marrs Aff. ¶ 41.)

42. With the launch of these branded products, Dey's marketing and sales efforts were almost entirely focused on promoting Dey's brands instead of its generics. (Marrs Aff. ¶ 42.)

B. DEY'S SUBJECT DRUGS

43. The First Amended Complaint in this action ("Am. Compl.") alleges claims against Dey arising from reimbursement by Medicare and Medicaid programs to providers for dispensing varying dosages, concentrations, and sizes of Dey's albuterol sulfate, cromolyn sodium, and ipratropium bromide (the "Subject Drugs"). (Reid Decl., Ex. 13, at ¶ 29.)

44. All of the Subject Drugs are generic drugs. (Marrs Aff. ¶ 46.)

45. The Subject Drugs are sold under a number of National Drug Codes (NDCs). NDCs are 11-digit codes that uniquely identify the drug by manufacturer, active ingredient, and package size. If the packaging of a drug is changed, new NDCs must be assigned; these are often referred to as successor NDCs. (Reid Decl., Ex. 13, at ¶ 29; Reid Decl., Ex. 14, at ¶ 29; Marrs Aff. ¶ 48.)

46. The following are the NDCs for the Subject Drugs with date of first and last shipment date as applicable:

Subject Drug	Formulation	Strength/ Package Size	NDC	First Shipment Date	Last Shipment Date
Albuterol Sulfate	metered dose inhaler	17g	49502-0303-17	Q1 1996	Q2 2000
Albuterol Sulfate	metered dose inhaler	17g, 90 mcg	49502-0333-17	Q1 2000	Q1 2003
Albuterol Sulfate	MDI refill	17g	49502-0303-27	Q4 1996	Q2 2000
Albuterol Sulfate	MDI refill	17g	49502-0333-27		

Subject Drug	Formulation	Strength/ Package Size	NDC	First Shipment Date	Last Shipment Date
Albuterol Sulfate	multi dose solution	.5%, 20 ml	49502-0196-20	Q1 1996	Q1 2000
Albuterol Sulfate	multi dose solution	.5%, 20 ml	49502-0105-01	Q2 1999	Q3 2003
Albuterol Sulfate	unit dose solution	.083%, 3ml, 25s	49502-0697-03	Q1 1992	Q2 2004
Albuterol Sulfate	unit dose solution	.083%, 3ml, 25s	49502-0697-24	Q1 2004	current
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 30s	49502-0697-33	Q4 1993	Q1 2004
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 30s	49502-0697-29	Q1 2004	current
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 30s	49502-0697-30	Q1 2005	current
Albuterol Sulfate	unit dose solution	.083%, 3ml, 60s	49502-0697-60	Q2 1992	Q3 2004
Albuterol Sulfate	unit dose solution	.083%, 3ml, 60s	49502-0697-61	Q1 2004	current
Cromolyn Sodium	unit dose solution	20 mg, 2 ml, 120s	49502-0689-12	Q2 1994	Q1 2004
Cromolyn Sodium	unit dose solution	20 mg, 2 ml, 60s	49502-0689-02	Q1 1994	Q3 2004
Cromolyn Sodium	unit dose solution	20 mg, 2 ml, 60s	49502-0689-61	Q1 2004	Q1 2008
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-03	Q1 1997	Q1 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-24	Q1 2004	Q2 2006
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-26	Q2 2006	current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-33	Q3 1997	Q1 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-29	Q1 2004	Q3 2005
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-31	Q2 2005	current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-30	Q1 2005	current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-60	Q1 1997	Q2 2004

Subject Drug	Formulation	Strength/ Package Size	NDC	First Shipment Date	Last Shipment Date
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-61	Q1 2004	Q3 2008
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-62	Q2 2005	current

(Reid Decl., Ex. 13, at ¶ 29; Declaration of Lauren J. Stiroh, Ph.D., dated June 25, 2009 ("Stiroh Decl."), ¶ 5.)

C. THE DISTRIBUTION OF DEY'S DRUGS

47. Dey sells the Subject Drugs to various classes of customers, including wholesalers, retail generic distributors, chain pharmacies, independent pharmacies, homecare pharmacies, hospitals, and long term care facilities. (Reid Decl., Ex. 5, at 35:11-36:6.)

48. Dey sells its drugs through two primary distribution channels – direct sales and indirect sales. (Reid Decl., Ex. 5, at 90:11-91:8.)

49. In a direct sale, Dey invoices its customer for a product and then ships the product directly from Dey's distribution center to that customer. (Reid Decl., Ex. 5, at 90:11-16.)

50. All sales to wholesalers as well as all sales to purchasers who can take delivery at their own distribution center are direct sales. (Reid Decl., Ex. 5, at 90:11-91:4.)

51. An indirect sale can be a sale that takes place between Dey's wholesale customer and one of Dey's contract customers who does not take direct delivery of the product. (Reid Decl., Ex. 5, at 90:11-91:8, 103:6-104.)

52. In an indirect sale with a contract, Dey negotiates a contract price with an indirect customer that will ultimately purchase Dey's product from a wholesaler. (Reid Decl., Ex. 5, at 90:11-91:1; 91:5-8; Reid Decl., Ex. 15, at 456:5-457:7.)

53. The contract price sets forth the price between Dey and the indirect customer, not the price between the indirect customer and the wholesaler. (Reid Decl., Ex. 5, at 99:18-100:5.)

54. Wholesalers also make indirect sales to customers with no contracts with Dey. In indirect sales where there is no contract with Dey, Dey has no visibility into the price paid by the wholesaler's customer. (Reid Decl., Ex. 16, at 104:10-12.)

II. COMPETITION IN THE GENERIC DRUG MARKET

55. In 1984, Congress enacted the Hatch-Waxman Act in an effort to encourage the use of generic drugs in the United States and to lower the cost of prescription drugs for American consumers through generic competition. (Reid Decl., Ex. 17; Declaration of W. David Bradford, dated June 25, 2009 ("Bradford Decl."), ¶¶ 3, 5, 6.).

56. Many states' Medicaid agencies have adopted drug formularies and mandatory generic substitution rules requiring the use of generics in the place of brands when available. (Bradford Decl. ¶ 12.)

57. As a generic drug manufacturer, Dey offers pharmaceutical products that are therapeutically equivalent to branded products. To be considered a generic equivalent to the brand drug and substitutable for the brand under generic substitution laws, a generic drug must have the same active ingredient, dosage strength and form, and route of administration as the equivalent brand drug. (*See, e.g.*, Reid Decl., Ex. 18, at vii-viii.)

58. The entry of generic manufacturers leads to increased competition, and as a result, prices decline. This prediction has been confirmed by many studies that show rapid decline in prices after the generic entry. (Bradford Decl. ¶¶ 8, 9, 10.)

59. Government reports and studies also find that the generic market is characterized by intense competition and that prices fall as generic entry increases. (*See* Reid Decl., Ex. 19; Reid Decl., Ex. 20, at 26; Reid Decl., Ex. 21, at xii–xiii; Bradford Decl. ¶ 9.)

60. Because of the savings that generics confer, payers, including Medicare and Medicaid, have put in place programs to encourage substitution of generic drugs. (Bradford Decl. ¶ 11.)

61. Before a pharmacy will have the incentive to substitute a less expensive generic for a more expensive brand, the pharmacy must earn at least as large of a dollar margin on the generic as on the brand. A mathematical consequence of this is that percentage margins for generic drugs will be generally higher than those on brand-name drugs. (Bradford Decl. ¶ 13.)

62. Thus dollar margins and spreads on generic prescription appear exaggerated when presented in percentage terms. The more relevant comparison from the perspective of the generic substitution is the dollar margin between the brand and generic prescription. (Bradford Decl. ¶ 13.)

63. The average prescription payment for a brand albuterol sulfate in 2000 in Massachusetts was $135.40. Similarly the average prescription payment for a generic (Dey) albuterol sulfate in 2000 in Massachusetts was $21.50. For the brand prescription, $13.50 reflects a 10% margin. (Bradford Decl. ¶ 13.)

64. If a payer wants the pharmacy to substitute a generic it will need to match the dollar margin on the brand. The same $13.50 reflects a 63% margin on the generic prescription. Furthermore, $13.50 reflects a 169% "spread" on the generic prescription. (Bradford Decl. ¶ 13.)

65. In the above example, switching to the generic drug results in a savings of $113 for Massachusetts Medicaid. To achieve that savings, Massachusetts must keep the pharmacy from losing revenue in the process. (Bradford Decl. ¶ 13.)

III. PRICING OF THE SUBJECT DRUGS

A. DEY'S PRICES AT LAUNCH

66. At launch, pricing for a generic, like Dey's albuterol, is set in relationship to the brand AWP. (Reid Decl., Ex. 5, at 129:22-130:11.)

67. Dey's practice of establishing AWPs for the Subject Drugs at a percentage lower than the therapeutically equivalent brand AWPs was consistent with what Dey believed to be the industry practice. (Reid Decl., Ex. 22, at 460:2-8.)

68. Ed Edelstein of First Databank informed Dey that a generic AWP must be at least 10% lower than the corresponding brand AWP in order to be listed as such by First DataBank. (Reid Decl., Ex. 5, at 129:22-131:14; Reid Decl., Ex. 23, at 731:17-24.)

69. According to Patricia Kay Morgan, former Manager of Editorial Services at First DataBank, there was a "perception in the industry" that a generic drug had to be priced at least 10 percent less than the brand price. (Reid Decl., Ex. 24, at 21:4-18.)

70. Accordingly, Dey set its AWPs for its generic drugs at approximately 10% of the brand AWP and left that price unchanged. (Reid Decl., Ex. 5, at 131:8-132:12.)

B. DEY'S WAC

71. Dey then set its WAC price for its generics as a percentage off Dey's AWP. (Reid Decl., Ex. 5, at 144:1-4; Reid Decl., Ex. 22, at 486:6-487:6.)

72. Figures A through K of Stiroh Declaration show Dey's WACs relative to its AWPs, AMPs, and FSS data. (Stiroh Decl., Figures A-K for prices through 2004; *see* confidential Figures A-K for prices through first quarter 2007.)

Dey's WAC is its Invoice Price to Wholesalers

73. WAC is Dey's invoice price to wholesalers. (Reid Decl., Ex. 5, at 75:22-76:3, 144:21-145:1; Reid Decl., Ex. 22, at 537:9-15; Reid Decl., Ex. 16, at 29:6-12, 31:14-16; Reid Decl., Ex. 15, at 501:2-17; Reid Decl., Ex. 25, at DL-0050108.)

74. As prices for the Subject Drugs decline over time, Dey reduces the WAC for those drugs. (Reid Decl., Ex. 26, at 662:6-12; Reid Decl., Ex. 26, at 823:13-19; Reid Decl., Ex. 5, at 136:16-21; Reid Decl., Ex. 27, at 8, 28.)

75. Dey regularly updated its WACs in a manner that directly reflected underlying pricing activity. (Reid Decl., Ex. 28, at 372:11-20; Reid Decl., Ex. 29, at DL-TX-0092446-50.)

76. Throughout the relevant time period, Dey reported WACs for the Subject Drugs to pricing compendia such as First DataBank, RedBook, and Medispan. (Marrs. Aff. ¶ 45.)

77. Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (Reid Decl., Ex. 5, at 137:6-17; Reid Decl., Ex. 30, at DL-0050063-30.)

78. For instance, after Dey launched the 25 unit package of its ipratropium bromide inhalation solution 0.02, 0.5 mg/2.5mL, (NDCs 49502068503, 49502068524) in 1997, it set the AWP for that product at $44.10 and did not change it throughout the relevant time period. (Stiroh Decl., Figure A).

79. By 1999, the WAC that Dey reported to pricing compendia for its ipratopium was $19.10 (Stiroh Decl., Figure A).

80. By 2001, the year from which the Government used prices to calculate the spreads in its Amended Complaint, the WAC that Dey reported was $15.00. (*See* Reid Decl., Ex. 13, at Ex. A; Stiroh Decl., Figure A).

Even After Discounts, A Majority of Dey's Sales to Wholesalers Are at or Near WAC

81. Approximately 90 percent of Dey's shipments to wholesalers are invoiced at Dey's WAC. (Stiroh Decl. ¶ 8; Stiroh Decl., Ex. 5.)

82. Dey's WACs are economically meaningful invoice prices to wholesalers. (Stiroh Decl. ¶ 6; Stiroh Decl., Exs. 5 and 6.)

83. More than 70 percent of Dey's sales to wholesalers over the time period for which data were available were within 5 percent of WAC, after adjusting for discounts and other price adjustments offered to wholesalers. (Stiroh Decl. ¶ 10, Ex. 6.)

Sales by Wholesalers to Off-Contract Customers Are Above WAC at Times

84. As Figure 2 and Appendix B to the Bradford Declaration illustrates, prices paid to wholesalers by off-contract customers can be above Dey's WAC. (Bradford Decl. Figure 2; Appendix B.)

C. DEY'S AMP

85. In 1991, Congress enacted the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") which created the Medicaid rebate program which lowered each state program's Medicaid costs through rebates from drug manufacturers pursuant to contract. OBRA 90 created the Average Manufacturer Price ("AMP"). (Reid Decl., Ex. 31.)

86. Meeting minutes from a November 27-28, 1990 meeting of a State Medicaid Directors' Association Pharmacy Reform TAG Meeting which addressed Medicaid rebates and which was co-chaired by Larry Reed, then Technical Director, Division of Pharmacy at HCFA/CMS, state that there was a "general discussion of state's need to know both AMP and best price for policy reasons (to establish a pharmacist reimbursement baseline) and to calculate rebate amounts." (*See* Reid Decl., Ex. 32, at AL-ARCH 0001124.)

87. Following the passage of OBRA 90, federal law required Dey to enter into a Rebate Agreement with the United States for Dey's products to be eligible for Medicaid coverage. (*See* 42 U.S.C.A. § 1396r-8(a)(1) (2009); Reid Decl., Ex. 33, at 615:11-18.)

88. On February 28, 1991 Dey and the Secretary of HHS, acting through CMS, entered into a Rebate Agreement. (Reid Decl., Ex. 34.) The terms of the Rebate Agreement applied retroactively to January 1, 1991. (Reid Decl., Ex. 34, at II(d).)

Dey Reports Average Manufacturer Price ("AMP")
to CMS Under the Medicaid Rebate Agreement

89. The Rebate Agreement requires Dey to provide to CMS on a quarterly basis the Average Manufacturer Price ("AMP"). (Reid Decl., Ex. 34 at II(d).) The Rebate Agreement sets forth a comprehensive definition of AMP as an average of the discounted unit price of a drug:

(a) "Average Manufacturer Price (AMP)" means, with respect to a

> Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(Reid Decl., Ex. 34, at § I(a) (Enclosure A).) Each of the capitalized terms incorporated in the AMP definition set forth above is further defined by the Rebate Agreement. (Reid Decl., Ex. 34, at § I .)

90. Dey has complied with its obligations and provided its AMP to CMS each quarter for each of the Generic Subject Drugs. (Marrs Aff. ¶ 43.)

91. Both former Administrators of CMS, Thomas Scully and Bruce Vladeck, stated that CMS employees could have compared Dey's AMPs to published prices for the Dey Subject Drugs to determine the difference between those prices. (Reid Decl., Ex. 33, at 617:12-619:22; Reid Decl., Ex. 35, at 464:7-465:10.)

92. For example, Mr. Scully testified as follows:

> Q. Okay. So, CMS employees, to nail this down, could sit down and take a look at the AMP for Albuterol, and compare that to the

> AWP for Albuterol, and calculate precisely the spread between those two points; right?
>
> MR. NEAL: I'll object to the form.
>
> MR. RIKLIN: Objection to form.
>
> A. I believe that's true, yes.
>
> Q. And that data existed within CMS Medicaid during the entire time that Dey's products were reimbursed under Medicaid; right?
>
> MR. NEAL: Objection as to form.
>
> A. I don't know what year we started collecting AMP, but whenever they started collecting AMP, yes.

(Reid Decl., Ex. 33, at 619:4-18).

Dey Pays Rebates to the States Based on AMP

93. Under the Rebate Agreement, Dey is required to pay rebates to states based on the AMP:

> In order for the Secretary to authorize that a State receive payments for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:
>
> (a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

(Reid Decl., Ex. 34, at §§ II, II(a).)

94. CMS uses the AMPs it receives from Dey to calculate the Unit Rebate Amount, or URA, an NDC-specific, per-unit amount. (Reid Decl., Ex. 34, at I (dd).)

95. CMS forwards the URAs on to state Medicaid programs, who in turn multiply the URAs by the number of units dispensed to determine the final rebate amount Dey will pay. (Reid Decl., Ex. 34, at 5; Reid Decl., Ex. 36, at 303:5-12.)

96. The state Medicaid programs then send Dey invoices for the rebate amounts owed. (Reid Decl., Ex. 34, at 5; Reid Decl., Ex. 36, at 303:5-12.)

States Can Determine Dey's AMP By Based on the Rebate Amount

97. The administrators in charge of running the Medicaid program have testified that States have had access to AMPs. (*See* Reid Decl., Ex. 35, at 461:12-15, 463:19-464:06; Reid Decl., Ex. 33, at 627:13-20.) Bruce Vladeck, the Administrator of HCFA from May 1993 to September 1997, testified:

> Q: So as far as you know, people within HCFA shared AMP data with state Medicaid agencies?
>
> A: That was my understanding.
>
> * * *
>
> Q: So it was entirely possible -- it was entirely possible for the heads of a state Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to what they were reimbursing for those drugs. That was entirely possible. Right?
>
> A: It's -- I don't know any reason why it wouldn't be possible.

(Reid Decl., Ex. 35, at 461:12-15, 463:19-464:06.)

98. Thomas Scully, the Administrator of CMS from May 2001 to December 2003, testified:

> Q: Did you ever tell any state that they should calculate their reimbursement methodology for Medicaid taking into account AMP data?
>
> A: No.

> Q: Why not?
>
> A: States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.

(Reid Decl., Ex. 33, at 627:13-20.)

99. For multisource generic drugs like the Subject Drugs, the unit rebate amount is calculated as 11% of the AMP. (*See* 42 U.S.C.A. 1396r-8(c)(3)(A – B) (2009); Reid Decl., Ex. 34, at 3.)

100. Knowing the unit rebate amount they receive, state Medicaid agencies could simply divide that amount by 11 percent to arrive at AMP. (*See* 42 U.S.C. 1396r-8(c)(3)(A – B) (2009).)[1]

101. Deirdre Duzor, the CMS Director of the Pharmacy Division for the Medicaid program, testified:

> Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
>
> * * *
>
> A: Yes. The AMPs have been fairly transparent for generic drugs.

(Reid Decl., Ex. 37, at 679:12-17.)

102. In a 2001 report, the OIG discussed the confidentiality of the AMPs as follows:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS

[1] Before January 1, 1994, the rebate for generic drugs was equal to 10 percent of the AMP. (*See* 42 U.S.C. 1396r-8(c)(3)(A – B) (2009).) Therefore, states could have determined the AMP before 1994 by dividing the unit rebate amount by 10 percent.

> reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(*See* Reid Decl., Ex. 38, at 22.)

103. Ann Maxwell, the Government's 30(b)(6) designee and a regional inspector general at the OIG, testified that this paragraph "accurately discusses the confidentiality provisions surrounding AMP." (Reid Decl., Ex. 39, at 129:1-131:3.)

AMP Tracks Dey's Published WAC

104. Dey's AMP reflects a discounted unit price calculated on the basis of specific government instructions. (Reid Decl., Ex. 15, at 534:4-16; Reid Decl., Ex. 5, at 168:6-169:9.)

105. As seen in Figures A through K to the Stiroh Declaration, Dey's AMP tracks slightly below Dey's published WAC for prices through 2004. *See* confidential Figures A-K for prices through 2007. (Stiroh Decl., Figures A-K.)

D. DEY'S AVERAGE SALES PRICE ("ASP")

106. Since 2005, every manufacturer is required to submit ASP information on a quarterly basis for each NDC covered under Medicare Part B. (Reid Decl., Ex. 40., at 2239-45.)

107. Prior to April 1, 2008, ASP was calculated by "(i) computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and (ii) dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products." (*See* 42 C.F.R. § 414.904 (2009); Reid Decl., Ex. 41.)

108. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. (Reid Decl., Ex. 42, at 3.)

109. Beginning in the first quarter of 2004, Dey reported its ASPs to CMS. (Marrs Aff. ¶ 44.)

E. FEDERAL SUPPLY SCHEDULE PRICES FOR THE SUBJECT DRUGS

110. The Government, through the Department of Veterans Affairs and the Department of Defense, negotiates Federal Supply Schedule ("FSS") prices for federal purchases of pharmaceuticals. (Reid Decl., Ex. 43, at 8-10.)

111. The FSS contains prices at which federal buyers are able to purchase pharmaceuticals. (Reid Decl., Ex. 43, at 8-10.) FSS prices for generic drugs are negotiated based on contract price and term information for most favored customers, which is requested from and provided by drug manufacturers, such as Dey. (Reid Decl., Ex. 43, at 8-10.)

112. As stated in the VA Federal Supply Schedules: "Product and/or service pricing as well as other terms/conditions negotiated for an FSS contract are based upon an offeror's commercial practices. The negotiation process begins with an evaluation (price analysis) of an offeror's most favored commercial customer (MFC) prices and related terms and conditions." (Reid Decl., Ex. 44, at Introduction.)

113. Administered by VA through multiple award contracts with manufacturers, the FSS for pharmaceuticals is a list of over 17,000 brand name and generic drug products and their prices. (Reid Decl., Ex. 43, at 9, n.5.)

114. The FSS prices are not confidential and recent prices are reported by the US Department of Veterans Affairs on its web site. (*See* Reid Decl., Ex. 45.)

115. FSS prices are lower than compendia-published prices. (Reid Decl., Ex. 43, at 9-10.)

116. The OIG examined FSS prices for albuterol in 1998. (Reid Decl., Ex. 46, at 7, 8.)

IV. PLAINTIFFS RECEIVED ADDITIONAL INFORMATION REGARDING THE INGREDIENT COST OF THE DEY SUBJECT DRUGS

A. OIG INVESTIGATIONS AND REPORTS ON THE SUBJECT DRUGS

OIG Information Regarding Dey's Albuterol

117. The OIG has published ten reports studying the acquisition cost of Albuterol:

- "Medicare Payments for Nebulizer Drugs" OEI-03-94-00390 (February 1996) (Reid Decl., Ex. 47);

- "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996) (Reid Decl., Ex. 48);
- "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996) (Reid Decl., Ex. 49);
- "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290 (December 1997) (Reid Decl., Ex. 50);
- "Are Medicare Allowances for Albuterol Sulfate Reasonable?" OEI-03-97-00292 (August 1998) (Reid Decl., Ex. 46);
- "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293 (November 1998) (Reid Decl., Ex. 51);
- "Medicare Reimbursement of Albuterol" OEI-03-00-00311 (June 2000) (Reid Decl., Ex. 52);
- "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001) (Reid Decl., Ex. 53);
- "Excessive Reimbursement for Albuterol" OEI-03-01-00410 (March 2002) (Reid Decl., Ex. 54); and
- "Update: Excessive Medicare Reimbursement for Albuterol" OEI-03-03-00510 (January 2004) (Reid Decl., Ex. 55.)

118. In "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996), the OIG concluded that members of pharmaceutical buying groups could purchase albuterol sulfate for between 56 and 70 percent lower than the $0.43 per milliliter paid by Medicare at the time. (Reid Decl., Ex. 48, at 5-6.)

119. In "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996), the OIG concluded that Medicare suppliers could acquire albuterol sulfate as low as $0.12 per milliliter, while the price paid by Medicare was $0.43 per milliliter. (Reid Decl., Ex. 49, at 6.)

120. In December, 1997, the OIG reported that the actual average wholesale price for albuterol sulfate, J7620, in 1995 was $0.19, $0.22 lower than the $0.41 average Medicare reimbursement amount for that time. (Reid Decl., Ex. 50, at Appendix B, page B-2.)

121. In August, 1998, the OIG reported that Medicare will pay between 56 and 550 percent more for albuterol than FSS prices available to the VA and up to 333 percent more than some pharmacies pay to acquire albuterol. (Reid Decl., Ex. 46, at 7, 8.)

122. In November, 1998, the OIG reported that the median price for the Department of Veterans Affairs (the "VA") to purchase albuterol sulfate unit dose was $0.12, while Medicare's median allowable price was $0.47, resulting in a 292 percent spread. (Reid Decl., Ex. 51, at Appendix B, page B-1.)

123. The OIG has also produced invoices for Dey's albuterol. During discovery, the Government produced working files for these reports, indicating that they bore the Bates prefixes HHD005 through HHD0014. (*See* Reid Decl., Ex. 56.)

124. For example, an internal OIG memorandum dated November 8, 1995 from "Karen" to "Rob," "Bob," and "Amy," discusses invoices the government received from Medicare suppliers for Dey's albuterol sulfate 0.083%. The memorandum annexes invoice prices for Dey's albuterol unit dose. (Reid Decl., Ex. 57.)

125. The memorandum notes that the lowest price suppliers pay to Dey for albuterol sulfate is $0.1167 per milliliter, and the highest price paid by suppliers for Dey's albuterol sulfate was $0.1667 per milliliter. (Reid Decl., Ex. 57, at HHD011-0915-16.)

126. The various tables annexed to the memorandum list prices for Dey's albuterol from manufacturers, suppliers, and wholesalers. (Reid Decl., Ex. 57.)

OIG Information Regarding Dey's Ipratropium

127. The Government has also specifically studied the actual acquisition cost of another of the Subject Drugs, ipratropium bromide, beginning at least as early as 1998, and the working files from the OIG indicate that the OIG also reviewed various prices for Dey's ipratropium. (*See, e.g.*, Reid Decl., Ex. 51.)

128. In "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293, the OIG found that the VA's median price for ipratropium bromide was $1.31 per mg, while Medicare's median allowable price was $3.34 per mg, resulting in a 155% difference. (Reid Decl., Ex. 51, at Appendix B, page B-1.)

129. A document produced from the OIG's working files, dated May 21, 1998, lists Federal Supply Schedule prices for several drugs, including Dey's albuterol sulfate and ipratropium bromide products. That document lists a Federal Supply Schedule price for Dey's ipratropium bromide 0.02% inhalation solution (NDC 49502-0685-60) of $40. (Reid Decl., Ex. 58.)

130. Another document bearing the same Bates prefix and dated January 1998 appears to be a print-out of various AWP prices for ipratropium from Red Book. (Reid Decl., Ex. 59.)

131. In 2001, 2002 and again in 2004, the OIG continued to find and to report that there were large spreads for ipratropium:

- In "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001), the OIG found that a median VA price was $0.84 per milligram, whereas the median Medicare allowable amount was $3.34, creating a spread of 297 percent. The report also found that the median catalog price for ipratropium was $1.53, creating a spread of 118 percent. (Reid Decl., Ex. 53, at Appendix D, page 16-17.)

- In "Excessive Medicare Reimbursement for Ipratropium Bromide" OEI-03-01-00411 (March 2002), the OIG reported that the median Medicare allowable cost for ipratropium bromide was $3.34, while the median VA price for ipratropium bromide was $0.66, resulting in a "spread" of 406 percent. The report also contained a chart, tracking the Medicare allowable amount against the VA prices between 1998 and 2001. The report also found that the median price for ipratropium appearing in wholesale catalogs was $0.82 per milligram, creating a spread of 307 percent between the catalog price and the Medicare allowable amount. (Reid Decl., Ex. 60, at 9-11.)

- In "Update: Excessive Medicare Reimbursement for Ipratropium Bromide" OIG-03-03-00520 (January 2004), the OIG found that Medicaid set a FUL for ipratropium bromide at $1.17 per mg, 65% less than the $3.34 that Medicare pays for the same drug. The median wholesaler price for that same drug is $0.57, and the median GPO price is $0.62. (Reid Decl., Ex. 61, at ii.)

OIG Information Regarding Dey's Cromolyn

132. The OIG working files also contain pricing information for Dey's cromolyn sodium. For example, a February, 1996 fax from Dr. Robert Zone of Palmetto to Robert Vito at the OIG contained a contract showing the 1994 price of Dey's cromolyn to be $60 per package. (Reid Decl., Ex. 62.)

133. Mary Riordan, counsel to the OIG, produced copies of a Pharmaceutical Buyers, Inc. catalog dated November 28, 1995, which listed contract prices for Dey's cromolyn at $28.00 per package. (Reid Decl., Ex. 63, at HHD194-1165.)

134. Ms. Riordan also produced a contract between Dey and Gerimed, a provider group purchasing organization, with an effective date of August 1, 1996, listing contract prices for its cromolyn at $25.00 and $49.00 per package. (Reid Decl., Ex. 64.)

135. The OIG also obtained invoices from 1999 from pharmacies for Dey's albuterol (NDC 49502-0689-02) in connection with its reviews of pharmacy acquisition costs in

states such as West Virginia and Indiana. (Reid Decl., Ex. 65, at HHD027-0342; Reid Decl., Ex. 66, at HHD028-0207.)

B. CONTRACT PRICING REQUESTED FROM VEN-A-CARE

136. In addition to the information it gathered through its own investigations, the Government requested and began receiving contract prices for inhalation drugs, including the Subject Drugs, from the relator in this case, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"). (Reid Decl., Ex. 67, at 860:14-863:1; 874:9-875:10; 876:8-20; Reid Decl., Ex. 68.) Ven-A-Care obtained the pricing information for Dey's drugs from wholesalers and group purchasing organizations ("GPO"). (Reid Decl., Ex. 67, at 786:11-788:13.)

137. For instance, a fax sent by Ven-A-Care to the OIG on March 19, 1996 contains both Dey's contract prices to a GPO as well as the AWPs for Dey's drugs. (Reid Decl., Ex. 68.) Robert Vito at the OIG requested this information to assist in the preparation of the OIG reports relating to albuterol pricing. (Reid Decl., Ex. 67, at 861:6-862:20.) The contract price for Dey's albuterol unit dose was $.13 per milliliter while at the same time the AWP was $.40 per milliliter, three times that of the contract price. (Reid Decl., Ex. 68, at 2, 3.) Dey's contract price for metered dose inhalers was $13.50 while AWP was $21.70. (Reid Decl., Ex. 68, at 2, 3.) The contract price for Dey's cromolyn was $.23 per milliliter while the AWP was $.35 per milliliter, more than one and a half times greater than the contract price. (Reid Decl., Ex. 68, at 2, 3.)

138. Throughout the relevant time period, Ven-A-Care continued to send the OIG wholesaler price information and GPO contract information for the Subject Drugs. (Reid

Decl., Ex. 70; Reid Decl., Ex. 71; Reid Decl., Ex. 72; Reid Decl., Ex. 73; Reid Decl., Ex. 74; Reid Decl., Ex. 75; Reid Decl., Ex. 76.)

139. As early as 1998, Ven-A-Care provided the OIG passwords to online electronic databases of wholesalers and GPOs, allowing the federal government access to all prices sold by various wholesalers and GPOs. (Reid Decl., Ex. 77, at 1094:9-21; 1095:15-22.) In January 2001, Ven-A-Care gave the federal government a laptop containing the Econolink database. (Reid Decl., Ex. 78, at 13:8-15; 18:23-20:10.) The laptop from Ven-A-Care gave the federal government a working database that gave them all the pricing information Ven-A-Care possessed. (Reid Decl., Ex. 78, at 76:20-77:20; 81:12-20.)

140. Ven-A-Care also forwarded to the federal government several sales circulars and advertisements showing that rebates were available for Dey's products. (Reid Decl., Ex. 67, at 926:9-13; *see also* Reid Decl., Ex. 71, at VAC MDL43586; Reid Decl., Ex. 67, at 883:6-9; Reid Decl., Ex. 79; Reid Decl., Ex. 67, at 925:1-9; Reid Decl., Ex. 80; Reid Decl., Ex. 67, at 927:17-21; Reid Decl., Ex. 81; Reid Decl., Ex. 67, at 955: 13-21; Reid Decl., Ex. 82; Reid Decl., Ex. 67, at 969:10-13.)

141. On March 19, 1998, Ven-A-Care made a presentation before the National Association of Medicaid Fraud Control Units (NAMFCU). (Reid Decl., Ex. 407:17-408:22.) Sign-in sheets demonstrate that representatives from every state except Alabama received the materials from this meeting. (Reid Decl., Ex. 84; Reid Decl., Ex. 85; Reid Decl., Ex. 86; Reid Decl., Ex. 67, at 1014:4-1016:18.) Around the same time, Ven-A-Care made a similar presentation to officials at CMS. (Reid Decl., Ex. 407:17-408:22.) Ven-A-Care made a similar presentation to CMS in 1995. (Reid Decl., Ex. 67, at 835:14-841:22.) At these presentations,

Ven-A-Care contended that AWPs and WACs exceeded the actual acquisition costs of Medicare and Medicaid providers, that there were mega-spreads between AWP and actual acquisition costs, and that drug manufacturers marketed the spread to gain market share. (Reid Decl., Ex. 77, at 1119:21-1120:16.)

142. Ven-A-Care filed a sealed *qui tam* FCA action against Dey on August 13, 1997, seeking to recover damages on behalf of both the Medicare and Medicaid programs arising from Dey's albuterol sulfate unit dose and cromolyn sodium. (Reid Decl., Ex. 94, at ¶¶ 120-121.) Pursuant to the procedural requirements of the FCA, Ven-A-Care was required to disclose this *qui tam* complaint and all the material evidence in within its possession to the federal government prior to the filing of the complaint. (*See* 31 U.S.C.A. § 3730(b)(2) (2009).) On December 9, 1999, Ven-A-Care filed an amended *qui tam* complaint which included allegations concerning Dey's ipratropium bromide. (Reid Decl., Ex. 94, at ¶¶ 141-142.)

143. The Government did not intervene within the original 60 day seal period provided by the FCA following the filing of these complaints and instead sought and obtained extensions of the seal period for nine years. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 392 (D. Mass. 2007). During the nine year seal period, the Government subpoenaed documents from Dey and other drug manufacturers (Reid Decl. Ex. 96, at ABT008-0340); created an electronic database for the storage and review of those documents (Reid Decl. Ex. 97, at ABT008-1069); coordinated discovery efforts with state Medicaid Fraud Control Units (*Id.*); interviewed witnesses (Reid Decl. Ex. 98, at ABT008-1040); retained an expert to assist with damages calculations (Reid Decl. Ex. 99, at 2); and developed a computer model to assess damages (Reid Decl. Ex. 100, at 5).

C. INFORMATION PROVIDED BY DEY IN RESPONSE TO SUBPOENAS

144. The OIG issued a first subpoena to Dey on or about October 31, 1997 and a second subpoena on or about July 27, 2000. (Marrs Aff. ¶ 49.)

145. Over an eight year period from October 1997 to September 2005, Dey produced or made available for inspection approximately a combined 2.3 million pages of documents on at least eight separate occasions to the HHS-OIG (most of which were also produced to Ven-A-Care in connection with the Texas and/or Florida pricing litigations). (Marrs Aff. ¶ 50.)

146. As of December, 1997, Dey had produced 2697 pages of documents in response to the OIG subpoena, which included various contract awards listing contract prices and other pricing information for many of the Subject Drugs. (Marrs Aff. ¶ 51.)

147. For example, Dey produced wholesale price lists, contract modifications, contract awards, and contract proposals for the Subject Drugs for customers such as Greater New York Hospital Association, Community Pharmacy Network, and Pharmaceutical Buyers, Inc. (Reid Decl., Ex. 101; Reid Decl., Ex. 102; Reid Decl., Ex. 103; Reid Decl., Ex. 104; Reid Decl., Ex. 105; Reid Decl., Ex. 106; Reid Decl., Ex. 107; Reid Decl., Ex. 108.)

D. DEY'S PRICE NOTIFICATION LETTERS

148. Since January 1999, Dey sent letters to state Medicaid administrators in which Dey explicitly described the nature of its published AWPs and WACs when new products were introduced or when prices were changed. (Reid Decl., Ex. 30; Reid Decl., Ex. 109; Reid Decl., Ex. 110; Reid Decl., Ex. 111; Reid Decl., Ex. 112; Reid Decl., Ex. 113; Reid Decl., Ex.

114; Reid Decl., Ex. 115; Reid Decl., Ex. 116; Reid Decl., Ex. 117; Reid Decl., Ex. 118; Reid Decl., Ex. 119; Reid Decl., Ex. 120.)

149. Dey has also sent letters with similar language to Medicare Durable Medical Equipment Regional Carriers ("DMERCs"). (Reid Decl., Ex. 111, at DEY-LABS0415397.)

150. Multiple states have produced similar letters which they received from Dey, such as Alabama, Connecticut, Illinois, Maryland, Texas, Virginia, and Wisconsin. (Alabama: Reid Decl., Ex. 121; Connecticut: Reid Decl., Ex. 122; Illinois: Reid Decl., Ex. 123; Maryland: Reid Decl., Ex. 124; Texas: Reid Decl., Ex. 125; Reid Decl., Ex. 126; Reid Decl., Ex. 127; Reid Decl., Ex. 128; Virginia: Reid Decl., Ex. 129; Wisconsin: Reid Decl., Ex. 130; Reid Decl., Ex. 131; Reid Decl., Ex. 132; Reid Decl., Ex. 133; Reid Decl., Ex. 134; Reid Decl., Ex. 135; Reid Decl., Ex. 136; Reid Decl., Ex. 137.)

151. For example, in one such letter dated August 1999, Robert Mozak, Dey's Executive Vice President for Sales and Marketing, wrote to state Medicaid administrators as well as regional Medicare benefits administrators, apprising them of a new NDC number for Dey's Albuterol Sulfate Inhalation Solution 0.5%. (Reid Decl., Ex. 111.)

152. The letter describes Dey's WAC as follows:

> As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees, and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be

> determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid.

(Reid Decl., Ex. 111 (emphasis in the original).)

153. The letter goes on to describe AWP as follows:

> Further, as you also know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

(Reid Decl., Ex. 111 (emphasis in the original).)

154. The letter closes with the following sentence: "If you need additional information, please feel free to contact Todd Galles, Senior Product Manager, at 800-755-5560, ext. 7450." (Reid Decl., Ex. 111.)

155. Todd Galles, the Dey contact person listed on the August 1999 letter discussed above, testified that he had never been contacted by anyone regarding the letter. (Reid Decl., Ex. 138, at 410:1-411:15.)

156. State Medicaid officials who recalled receiving such letters from Dey testified that they never contacted anyone from Dey about the statements made in the letters. (Alabama: Reid Decl., Ex. 139, at 278:4-279:21, 280:4-281:20; Arkansas: Reid Decl., Ex. 140, at 537:14-539:5; California: Reid Decl., Ex. 141, at 267:13-19; Delaware: Reid Decl., Ex. 142, at 218:4-219:21; Reid Decl., Ex. 143, at 489:1-490:14; Michigan: Reid Decl., Ex. 144, at 245:12-13, 245:17-246:20; Nebraska: Reid Decl., Ex. 145, at 264:18-265:3, 265:11-266:11; North Carolina: Reid Decl., Ex. 146, at 337:3-339:18; Oregon: Reid Decl., Ex. 147, at 169:4-170:5;

Tennessee: Reid Decl., Ex. 148, at 305:18-306:17; Vermont: Reid Decl., Ex. 149, at 319:18-321:15; Virginia: Reid Decl., Ex. 150, at 301:4-15; Wisconsin: Reid Decl., Ex. 151, at 150:21-151:7, 153:11-17, 155:15-22, 157:8-18, 159:15-160:6.)

157. State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (*See* Reid Decl., Ex. 144, at 245:12-13; 245:17-246:20.) Accordingly, Dey had no reason to believe there was any doubt that Medicaid and Medicare officials knew WAC represented the undiscounted list price used on invoices to wholesalers and its AWP was not changed over time and was not a price which would be charged or paid. *See, e.g.*, letter from Robert Mozak to Martha McNeill at the Texas Department of Health that Dey expected that its "explanatory language" that WAC excluded discounts would come as "no surprise" to the agency. (Reid Decl., Ex. 152.)

158. Carolyn Helton of CIGNA, one of the DMERCs, also recalled receiving letters from Dey but did not call Dey in response. (Reid Decl., Ex. 153, at 117:1-118:8.)

V. THE MEDICARE PROGRAM

A. MEDICARE GENERALLY

159. The Medicare system was enacted in 1965 as part of Title XVIII of the Social Security Act. Medicare is a health insurance program for people over the age of 65, people with certain disabilities, or people with End-Stage Renal Disease. Medicare Part A, also known as hospital insurance, helps cover inpatient care in hospitals. Medicare Part B, also known as medical insurance, helps cover doctors' services and outpatient care, and includes coverage for durable medical equipment and specific drug products. (Reid Decl., Ex. 13, at ¶¶ 24-25.)

160. Medicare Part B generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (*see* 42 C.F.R. § 410.26 (2009) (e.g., certain oncology drugs)); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. (*see* 42 C.F.R. § 405.517 (2009); Reid Decl., Ex. 13, at ¶ 26.)

161. Ensuring beneficiary's access to necessary medical care is a goal of the Medicare program. "The DRA requires CMS to ensure that Medicare and Medicaid beneficiaries continue to have access to high-quality medical care in the most appropriate setting." (Reid Decl., Ex. 154, at 11.)

B. DMERCS AND CARRIERS

162. The Medicare program is administered by the federal agency CMS - formerly HCFA. During the relevant time period, CMS contracted with private insurance carriers to administer and pay Part B claims from the Medicare Trust Fund. In this capacity, the carriers act on behalf of CMS. (*See* 42 U.S.C.A. § 1395u (2009); 42 C.F.R. § 421.5(b) (2009); Reid Decl., Ex. 13, at ¶¶ 10, 25, 27.)

163. Originally, CMS contracted with fiscal intermediaries to process drug claims submitted by providers for drugs covered under Medicare Part B. However, in 1993, increased utilization of drugs used with durable medical equipment and the existence of unique provider groups led HCFA to create a system with separate fiscal intermediaries to process DME related claims. HCFA created four regions, each with a separate fiscal intermediary. The regional fiscal intermediaries are referred to as Durable Medical Equipment Regional Carriers

("DMERCs"). These institutions are not the same carriers as those that handle other Medicare payments. (Reid Decl., Ex. 47, at 1-2; Bradford ¶ 32.)

164. Dey's inhalation therapy Subject Drugs at issue in the Government's Medicare claim are all administered via a nebulizer which is classified as durable medical equipment and covered under Medicare Part B. Reimbursement for these drugs is processed through the DMERCs. (Reid Decl., Ex. 13, at ¶¶ 26-29).

165. Carriers and DMERCs are agents of CMS, and one way in which CMS/HCFA communicated its directives to the Carriers and DMERCs was through Program Memoranda. The DMERCs would use the program memoranda to set their reimbursement levels. (Reid Decl., Ex 13, at ¶ 27; Reid Decl., Ex. 155, at 107:20-109:6; Reid Decl., Ex. 153, at 126:10-18,139:22-140:11; Reid Decl., Ex. 156, at 144:18-145:3.)

166. The government established four DMERCs which cover four separate regions. (*See* 42 C.F.R. § 421.210 (2009); Reid Decl., Ex. 49, at 1-2; Bradford ¶ 32.)

C. HCPCS CODES AND PRICING ARRAYS

167. Medicare generally reimburses for covered prescription drugs by using a 5-digit alphanumeric code, the Healthcare Common Procedural Coding System ("HCPCS" or "HCPCS Code"). (Reid Decl., Ex. 13, at ¶ 33.)

168. Unlike NDC codes, the HCPCS are not unique to product size, packaging or dose. A single HCPCS code can encompass more than one NDC, and therefore may include the products of different generic manufacturers selling similar multi-source drugs. (Reid Decl., Ex. 157, at 2-3.)

169. Medicare drug payments are not made for individual NDCs. Similarly, payment levels are not determined solely on individual NDC prices. Instead, payment levels are set at the procedural, or HCPCS, level. Thus for multi-source drugs, CMS uses the published prices available to set the reimbursement level for all drugs included in the HCPCS. Many manufacturers' products may be included in any one HCPCS code. (Reid Decl., Ex. 157, at 2-3.)

170. To determine the ingredient payment level, the DMERCs collected AWPs for NDCs relevant to each HCPCS from pricing compendia. This list of NDCs and prices was commonly known as the pricing array. Each DMERC compiled a pricing array for each HCPCS on a quarterly basis and calculated the median generic or lowest brand price to determine the allowed reimbursement level. (Reid Decl., Ex. 158, at 272:1-277:19; Reid Decl., Ex. 159.)

171. Although payment policies for Medicare Part B are set at the Federal level, regional DMERCs had exercised discretion in implementing these policies. Carolyn Helton of CIGNA testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Reid Decl., Ex. 153, at 151:7-17; Bradford ¶ 33.)

172. Because various DMERCs used their discretion to compile data for the arrays, there are differences in the prices listed in the arrays across DMERCs. Cheryl Eiler of Administar Federal, one of the DMERCs, testified: "We would try to use the products that best suited the narrative description of the HCPCS code that we were given in order to calculate the fee. And sometimes other regions may have used a different product than I would have used, and that would be the discrepancy, or used a different package." (Reid Decl., Ex. 292, at 426:20-427:-4; Bradford ¶ 33.)

173. The four regional DMERCs began to coordinate with each other on the construction of the quarterly pricing arrays. (Reid Decl., Ex. 158, at 300:4-304:5; Reid Decl., Ex. 155, at 153:1-17.)

D. HISTORY OF MEDICARE REIMBURSEMENT METHODOLOGIES

174. Throughout the period at issue, Medicare would only use the AWP basis if it were lower than the provider billed charge. (*See* 42 C.F.R. § 405.517 (2009); Reid Decl., Ex. 160; Reid Decl., Ex. 161; Reid Decl., Ex. 162, at 192:17-195:3; Reid Decl., Ex. 163, at 325:1-7.)

175. From 1992 to 1997, the Medicare ingredient reimbursement formula was the lower of (1) the billed charge from the provider, or (2) the lower of the Estimated Acquisition Cost ("EAC") or the median AWP of all of the generic forms of the products in the relevant code. (Reid Decl., Ex. 164; Reid Decl., Ex. 162, at 192:17-195:3; Reid Decl., Ex. 163, at 325:1-7.)

176. According to the Medicare regulations, EAC was to be based on surveys of actual invoice prices paid by providers. These surveys would have provided a basis of reimbursement independent of manufacturer published prices. In practice, the EAC component of Medicare Part B drug reimbursement allowable was never utilized. Instead, AWP published in the Red Book was used to determine the median AWP among all the generic multi-source drugs relevant to the HCPCS. (Reid Decl., Ex. 164; Reid Decl., Ex. 165, at 79:8-15; Reid Decl., Ex. 166, at 54:5-55:2; Reid Decl., Ex. 49, at 10; Reid Decl., Ex. 167, at 338:4-339:15.)

177. In 1996 and 1997, the OIG published four reports which demonstrated that the acquisition costs for the Dey Subject Drugs were far below AWP: (1) "Medicare Payments for Nebulizer Drugs" OEI-03-94-00390 (February 1996) (Reid Decl., Ex. 47); (2) "A

Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996) (Reid Decl., Ex. 48); (3) "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996) (Reid Decl., Ex. 49); and (4) "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290 (December 1997) (Reid Decl., Ex. 50).

178. In 1997, Congress refused to implement a portion of the Balanced Budget Act, the Medicare reimbursement proposal by President Clinton which would reimburse for prescription drugs at actual acquisition cost with an increase in dispensing fee. (Reid Decl., Ex. 168; Reid Decl., Ex. 169, at 181:5-182:21.)

179. In 1998, the OIG published two reports which examined the acquisition costs for the Dey Subject Drugs, finding them to be far below AWP: "Are Medicare Allowances for Albuterol Sulfate Reasonable?" OEI-03-97-00292 (August 1998) (Reid Decl., Ex. 46); and "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293 (November 1998) (Reid Decl., Ex. 51).

180. In January 1998, Congress changed the reimbursement formula to the lesser of the billed charge or 95 percent of the median AWP for drugs within a single HCPCS code. This information was transmitted to carriers and DMERCs in a Program Memoranda dated January, 1998 which states: "Effective January 1, 1998, pay for drugs and biologicals not paid on a cost or prospective payment basis at the lower of the billed charge or 95 percent of the AWP. This change in payment allowance recognizes the fact that the AWP is not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary. Part B deductible and coinsurance requirements apply." (Reid Decl., Ex. 160; Reid Decl., Ex. 161.)

181. President Clinton again proposed a change in his Balanced Budget Act of 1998 to actual acquisition cost, but Congress once again did not adopt the actual acquisition cost methodology proposed by President Clinton and instead continued reimbursement based on 95% of AWP. (Reid Decl., Ex. 170.)

182. Former HCFA Administrator Nancy-Ann DeParle testified as follows:

> Q. . . . HCFA had, in fact, included a provision in the President's 1998 Budget Bill, or the President included the provision in that budget bill, that would have eliminated the mark-up of the drugs billed by Medicare by requiring physicians to bill the program the actual acquisition costs. Do you see that?
>
> A. Yes, I do.
>
> Q. Do you recall that that was, in fact, included in the President's proposed budget for 1998?
>
> A. Yes.
>
> Q. And Congress chose not to enact that provision; correct?
>
> MS. YAVELBERG: Objection; form.
>
> A. It was not enacted.
>
> Q. I mean, Congress did not enact the provision; right?
>
> A. That's correct.
>
> Q. Congress instead enacted the provision providing for a payment at 95 percent of AWP; right?
>
> A. Yes.
>
> Q. And requiring it to pay at 95 percent AWP; correct?
>
> A. Yes.

(Reid Decl., Ex. 169, at 134:1-135:5.)

183. CMS has consistently defined AWP as "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan" in its instructions to carriers. (Reid Decl., Ex. 160; Reid Decl., Ex. 171; Reid Decl., Ex. 172; Reid Decl., Ex. 173; Reid Decl., Ex. 174.)

184. The OIG issued another report studying the acquisition costs for the Dey Subject Drugs in January, 2001, "Medicare Reimbursement of Prescription Drugs" (Reid Decl., Ex. 53.)

185. From 1999 to 2003, regulations mandated that Medicare reimburse Part B covered drugs at 95 percent of the lower of the median published AWP for all generic forms of the drug or the AWP of the least expensive brand-name drug. (*See* Reid Decl., Ex. 175; Reid Decl., Ex. 176.)

186. Program Memoranda AB-98-76 implemented these regulations and instructed carriers and DMERCs to calculate the median AWP as "the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP." (Reid Decl., Ex. 171.)

187. CMS continuously restated this formula for calculating the median AWP by issuing a September 1999 Program Memorandum, a November 14, 2000 Program Memoranda, and a May 22, 2002 Program Memoranda instructing Carriers and DMERCs to use AWP as set forth in the compendia and to calculate AWP by comparing the generic median with the lowest brand name product AWP. (Reid Decl., Ex. 172; Reid Decl., Ex. 173; Reid Decl., Ex. 175.)

188. The United States' 30(b)(6) designee, Donald Thompson, testified that CMS "develops Medicare Part B payment policy through notice and comment rule making. And

the policies would be contained in the rule making documents. The agency issued operational instructions to its claim processing contractors with respect to implementing those policies." (Reid Decl., Ex. 177, at 246:17-247:1.)

189. Mr. Thompson defined operational instructions to include the program memoranda sent to DMERCs and Carriers. (Reid Decl., Ex. 177, at 67:8-18.)

190. During 2004, regulations mandated that Medicare reimburse at a percentage of AWP dictated by statute, which, for the Dey Subject Drugs, was 80 percent. (Reid Decl., Ex. 178.)

E. INHERENT REASONABLENESS

191. CMS has the authority to adjust Medicare reimbursement payments that are not "inherently reasonable." 42 U.S.C.A. § 1395u(b)(8) (2009). This provision is known as the 'inherent reasonableness' clause. (Reid Decl., Ex. 179, at 2-4; Reid Decl., Ex. 55.)

192. In 1998, in response to the inherent reasonableness clause, the DMERCs surveyed the prices paid by providers for several products, including albuterol sulfate, reimbursed under Medicare Part B. (Reid Decl., Ex. 179, at 3-5; Reid Decl., Ex. 55.)

193. As a result of the survey the internal medical director for region D recommended that an "… Inherent Reasonableness reduction of 15% in 1998 for albuterol sulfate 0.083% is clearly warranted and supportable." (Reid Decl., Ex. 180, at 0216.)

194. In 1999, Congress passed legislation prohibiting HCFA from using the inherent reasonableness clause until the GAO conducted a study to examine the HCFA's effort. Among the questions posed by Congress for the GAO study was the issue of access due to the proposed reduced reimbursement levels. (Reid Decl., Ex. 179, at 2-3.)

F. MEDICARE'S USE OF THE DOJ AWPs

195. On September 8, 2000, CMS issued a program memorandum which announced alternative AWPs calculated "from wholesalers' catalogs that list the prices at which the wholesaler sells the respective products." (Reid Decl., Ex. 181.)

196. According to the program memorandum "[t]he DOJ has indicated that these are more accurate wholesale prices for these drugs. Furthermore, the DOJ has indicated that because purchasers often receive further discounts below the advertised wholesale catalog price, either from a wholesaler or from the drug manufacturer directly, actual acquisition costs may be lower. The DOJ indicates that some physicians and suppliers obtain drugs at prices lower than the wholesale catalog prices through Group Purchasing Organizations (GPO)." (Reid Decl., Ex. 181.)

197. The revised AWPs included the specific example of albuterol: "For example, the DOJ data from wholesale catalogs indicates an average wholesale price of $22 for one albuterol sulfate NDC which is substantially less than the $73 average wholesale price in the Redbook and compares to $15 from a GPO. These data are generally consistent with findings from OIG reports." (Reid Decl., Ex. 181.)

198. CMS issued lower revised AWPs for Dey's then current albuterol NDCs and Dey's then current cromolyn NDCs. (Reid Decl., Ex. 181.)

199. An internal document shows that HCFA estimated that these lower prices would result in savings of roughly $650 million out of the total $1.8 billion in expenditures on drugs with a DOJ revised AWP – as potential savings of just over 36%. The agency documents

further states that "[w]hile we believe that Medicare overpays for the drugs identified by DOJ, we must also assure continued beneficiary access to these drugs." (Reid Decl., Ex. 182.)

200. Nancy-Ann DeParle, HCFA Administrator in 2000, testified that she personally suspended these lower AWPs for certain drugs. (Reid Decl., Ex. 169, at 294:4-21.)

201. Ms. DeParle testified that she "couldn't and would not risk a cancer patient not being able to get his or her chemotherapy." (Reid Decl., Ex. 169, at 287:9-11.)

202. On November 17, 2000, a little over two months after they were first announced, Medicare suspended use of all DOJ AWPs, stating "[w]hile we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source." (Reid Decl., Ex. 183.)

G. THE MEDICARE MODERNIZATION ACT OF 2003 AND ASSOCIATED DISPENSING FEE CHANGES

203. In 2005, Medicare began reimbursing providers for the ingredient cost based on a markup (106 percent) over the Medicare ASP. (*See* 42 U.S.C.A. § 1395w-3a (2009).)

204. The change in reimbursement formula from 95% of AWP to 106% of ASP resulted in lower payments for the ingredient cost of drugs. Donald Thompson, the Government's 30(b)(6) witness, testified that the payment rate that was developed under the ASP resulted in payments that were lower than the payments that were made under the prior system. (Reid Decl., Ex. 177, at 274:10-15.)

205. Prior to reforms introduced in 2005 under the MMA, the dispensing fee allowed for inhalation drugs was $5.00. (Reid Decl., Ex. 177, at 272:18-273:7.)

206. Once ASP methodology was implemented, the drug dispensing fee for inhalation drugs was to be increased from $5 to a $57 monthly fee (or $80 90-day fee), effective in 2005. (Reid Decl., Ex. 184; Reid Decl., Ex. 185.)

VI. THE MEDICAID PROGRAM

A. MEDICAID ALLOWS STATES FLEXIBILITY TO DETERMINE THEIR REIMBURSEMENT RATES SUBJECT TO CERTAIN CONSTRAINTS

207. The Medicaid program was signed into law in 1965 as part of Title XIX of the Social Security Act and is a joint federal-state program that provides medical assistance to financially needy patients. (*See* 42 U.S.C.A. § 1396-1 (2009).)

208. The Medicaid program is jointly funded by states and the federal government. The federal government pays for a share of each state's Medicaid program expenditures which ranges from 50% to 83%. (*See* 42 U.S.C.A. § 1396d(b) (2009).)

209. In 1987, CMS, then known as the Health Care Financing Administration ("HCFA"), after a Task Force report and recommendation, enacted regulations 42 C.F.R §§ 447.301 to 447.333.

210. CMS provides individual states substantial discretion in designing their Medicaid programs. (*See* 42 C.F.R § 447.502 (2009); *See* 42 C.F.R § 447.302 (2009); *See* 42 C.F.R § 447.304 (2009); *See* 42 C.F.R § 447.512 (2009); *See* 42 C.F.R § 447.514 (2009); *See* 42 C.F.R § 447.518 (2009).)

211. State Medicaid agencies must act in accordance with their State Plan, which CMS reviews and approves annually. (*See* 42 C.F.R § 447.201 (2009); *See* 42 C.F.R § 447.518 (2009); Reid Decl., Ex. 13, at ¶ 20.)

212. However, within the broad federal requirements set by CMS, states have considerable flexibility in designing their State Plans. (Reid Decl., Ex. 186, at 431:4-9; Reid Decl., Ex. 187, at HHC002-0565.)

213. In 1989, Fred Schutzman, the Director, Bureau of Quality Control of HCFA requested that all HCFA regional administrators conduct a survey of each state's drug reimbursement policies using an attached survey form. The Glossary for the survey, dated March 23, 1989, defines "Average Wholesale Price" as "Published prices from Red Book, Blue Book or Medi-span. These are wholly fictitious prices similar to the sticker price on a new car." The surveys were completed at the regional level and returned to HCFA. (Reid Decl., Ex. 188, at HHD0084-0010.)

214. Bruce Vladeck, Administrator of CMS from 1993 to 1997, testified that states had leeway to be able to determine the specific ingredient reimbursement basis that they wanted, as long as it was acceptable to the federal government, and the government approved a variety of reimbursement methods that were consistent to federal law. (Reid Decl., Ex. 35, at 433:8-449:12.)

215. Mr. Vladeck testified as follows:

> A. HCFA approved state plans that paid on some basis relative to AWP, because that's what the statute provided for.
>
> Q. And in doing that you were approving plans that had the spread built into the reimbursement methodology. Right?
>
> MS. BROOKER: Objection. Form.
>
> A. Again, I would say that had a spread built into the reimbursement methodology.
>
> Q. Fine. But you also had one state, at least, that had no spread. Right?

MS. BROOKER: Objection. Form.

MR. BREEN: Objection. Form.

A. Yes, that's correct.

(Reid Decl., Ex. 35, at 448:21-449:12.)

216. Thomas Scully, Administrator of CMS from 2001 to January 2004, testified that it was CMS's policy to let the states make their own determination of what levels to reimburse providers at, and that it was up to the states' discretion whether they decided to reimburse at AWP minus 10% when CMS and the state knew that actual acquisition cost was more like AWP minus 40%. (Reid Decl., Ex. 189, at 209:11-210:15.)

"In the Aggregate"

217. For multiple source drugs subject to an upper limit established by HCFA, the 1987 regulations limited payment in the aggregate, across all drugs, to the amount that would result from the application of the specific limits established by HCFA plus a reasonable dispensing fee. (Reid Decl., Ex. 190.)

218. For all other drugs not subject to a Federal Upper Limit ("FUL"), a state agency's payment for all "other drugs" "must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) EAC plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public." (*See* 42 C.F.R. § 447.512(b) (2009).)

219. The regulations define "Estimated acquisition cost" to be a state agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold

by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." (*See* 42 C.F.R. § 447.502 (2009).)

Access to Care

220. A state agency's reimbursement methodologies are subject to an access constraint: "The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." (*See* 42 C.F.R. § 447.204 (2009).)

221. Accordingly, state Medicaid agency personnel attempt to balance at least two competing goals when making policy decisions to set reimbursement rates: 1) achieve sufficient access to quality health care for the enrollees, and 2) administer the program within the budget constraints imposed by the state legislature. (Reid Decl., Ex. 191, at 108:3-109:13; Reid Decl., Ex. 192, at 307:13-308:5; Reid Decl., Ex. 140, at 464:3-465:7; Reid Decl., Ex. 193, at 49:10-51:18.)

B. STATES HAVE MANY TOOLS TO SET THEIR TOTAL EXPENDITURES FOR PRESCRIPTION DRUGS AT A LEVEL OF THEIR CHOOSING

Rebate Agreements

222. The Medicaid program controls costs by obtaining rebates from drug manufacturers and rebates factor into the rate set for prescription drugs. (Reid Decl., Ex. 38, at 4.)

223. In addition, some states have entered into supplemental rebate agreements with manufacturers which require manufacturers to submit their AMPs to the state and pay an

additional amount beyond what the manufacturers are already required to pay under the OBRA 90 rebate agreement. (Reid Decl., Ex. 33, at 667:9-668:5.)

224. For example, Texas Government Code § 531.070 regarding supplemental rebates states: "[i]n negotiating terms for a supplemental rebate, the commission shall use the average manufacturer price (AMP), as defined in Section 1396r-8(k)(1) of the Omnibus Budget Reconciliation Act of 1990, as the cost basis for the product." (*See* Tex. Gov't Code Ann. § 531.070(m) (Vernon 2009).)

State MAC Programs

225. State MAC programs have been in existence since the 1970s. For example, a MAC program has been in place since 1976 in Maryland. By the early 1990s, 22 states had MAC programs for generic drugs. The number of states with a MAC program has increased steadily over the past decade, and by 2005, there were 44 states that had enacted MAC programs. (Bradford Decl. ¶ 24.)

226. CMS encourages states to adopt state-specific MACs to respond to and benefit from competitive commercial discounting. ((*See* Reid Decl., Ex. 194, at 28,653) ("We hope that the State agencies will be innovative in these programs and find ways to assure the availability at reasonable prices of multiple-source drugs…State agencies may initiate or retain already existing so-called 'mini-MAC' programs, which they have established on specific drugs either at levels lower than those established under the current Federal MAC limits or on drugs not now covered by MAC limits.").)

227. Of the states with claims data, 26 out of the 32 states had a state MAC in effect for some of the drugs at issue for some time period. (Bradford Decl. ¶ 25; Bradford Decl. Figure 7.)

228. For the states for which Dr. Bradford had state-level claims data, approximately 8.8 percent of claims for the Subject Drugs for which there is claims data in the record are reimbursed on the basis of a state MAC. (Bradford Decl., Figure 5.)

229. Much of the MAC data is missing or gone as a result of the Government's failure to preserve it while this case remained sealed for nine years. Dey hereby incorporates its Motion for a Finding of Spoliation and for Sanctions (Docket 6109), Memorandum of Law in Support of its Motion for a Finding of Spoliation and for Sanctions (Docket 6110), and supporting Declaration of Sarah L. Reid (Docket 6111).

230. There is substantial variation among state MAC programs. For example, Arkansas' state MACs are based on pharmacies' actual invoice prices, not AWPs or WACs. (Reid Decl., Ex. 192, at 65:3-11, 248:11-15, 250:9-251:4 ("[MACs] are based on what the pharmacy says they have paid for the product").)

231. Maine's MACs are based on pharmacies' acquisition costs ("the amount of money it costs the pharmacy to acquire a medication"). (Reid Decl., Ex. 195, at 94:5-98:3.)

232. Minnesota's MACs are based on actual acquisition costs that were provided by a group of pharmacies. (Reid Decl., Ex. 196, at 64:13-66:19.)

233. Wisconsin's MACs are based on wholesaler selling prices that are provided by wholesalers. (Reid Decl., Ex. 197, at 16:10-17:14, 61:3-64:22, 160:9-161:15.)

234. In Georgia, MACs are determined by pharmacy benefit managers who have their own proprietary methods for calculating the MACs, which they don't share with the State. (Reid Decl., Ex. 198, at 67:12-68:22, 207:3-13; 306:13-307:21.)

235. In all of the following states, MACs were based on acquisition costs, proprietary Medicaid agency formulas, private contractor data and calculations, provider invoices, or other methods that did not rely exclusively on the published prices for Dey's drugs: Alabama (Reid Decl., Ex. 271; Reid Decl., Ex.272; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Arkansas (Reid Decl., Ex. 192, at 65:3-11, 248:11-15, 250:9-251:4); California (after September 2002) (Reid Decl., Ex. 274, at 250:8-251:10); Connecticut (Reid Decl., Ex. 275, at 88:19-89:2); Florida (Reid Decl., Ex. 276, at 231:18-233:7); Georgia (Reid Decl., Ex. 198, at 67:12-68:12, 207:3-13; 306:13-307:21); Hawaii (Reid Decl., Ex. 277, at 392:22-393:3; 395:3-6); Idaho (Reid Decl., Ex. 278; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Illinois (after March 2005) (Reid Decl., Ex. 213, at 55:14-56:10; Reid Decl., Ex. 279, at 5-6; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Indiana (Reid Decl., Ex. 280, at 398:3-400:21; 652:12-653:15; Reid Decl., Ex. 281, at 134:21-135:12); Iowa (Reid Decl., Ex. 282; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Maine (Reid Decl., Ex. 195, at 94:5-98:3); Maryland (MAC program called the IDC program in Maryland) (Reid Decl., Ex. 216, at 201:14-205:12, 320:2-10); Michigan (Reid Decl., Ex. 283, at 37:14-39:9; Reid Decl., Ex. 144, at 49:4-9, 144:10-145:22); Minnesota (Reid Decl., Ex. 196, at 64:13-66:19); Missouri (Missouri has a "Missouri MAC" program) (Reid Decl., Ex. 284, at 38:12-25); Nebraska (Reid Decl., Ex. 145 at 130:10-134:10); Nevada (Reid Decl., Ex. 285, at 515:20-516:10, 524:4-8); New Hampshire (Reid Decl., Ex. 259, at 66:11-67:15, 169:15-170:3); North Carolina (Reid Decl., Ex. 146, at

261:6-266:2); North Dakota (Reid Decl., Ex. 220, at 96:21-98:12; 101:2-102:13; 112:21-113:21, 127:7-129:20); Ohio (Reid Decl., Ex. 221, at 158:1-161:18); Oregon (Reid Decl., Ex. 223, at 173:19-174:3, 177:18-21); South Dakota (Reid Decl., Ex. 225, at 98:19-99:14); Tennessee (Reid Decl., Ex. 148, at 106:18-109:11); Vermont (Reid Decl., Ex. 149, at 197:13-198:15); Washington (Reid Decl., Ex. 226, at 105:14-108:18); Wisconsin (Reid Decl., Ex. 197, at 15:21-17:14, 61:3-64:10, 74:9-18, 193:8-12, 199:1-10, 205:2-207:14); and Wyoming (Reid Decl., Ex. 227, at 233:19-234:16).

236. Plaintiffs have failed to provide evidence that any of the following states set MACs based on published prices of Dey's drugs: Kansas, Mississippi, New York, South Carolina, and Utah.

237. The following states used published prices to set MACs, but Plaintiffs have failed to produce any evidence that Dey's published prices had any material effect on the amounts at which those MACs were set: Alabama (Reid Decl., Ex. 286, at 761:22-763:11); California (before September 2002) (Reid Decl., Ex. 274, at 216:11-217:14); Delaware (Reid Decl., Ex. 142, at 102:18-106:1, 127:8-132:2; Reid Decl., Ex. 143, at 404:8-14, 463:7-20); Illinois (before March 2005) (Reid Decl., Ex. 213, at 55:14-56:10; Reid Decl., Ex. 279, at 5-6); Kentucky (Reid Decl., Ex. 287); Louisiana (Reid Decl., Ex. 215, at 88:13-89:11); Massachusetts (Reid Decl., Ex. 288; Reid Decl., Ex. 289); New Mexico (Reid Decl., Ex. 219, at 286:2-287:8); Pennsylvania (Reid Decl., Ex. 290); and Virginia (Reid Decl., Ex. 150, at 33:18-34:18).

The Federal Upper Limit

238. Federal Medicaid officials began to address the unique features of the generic market in the 1970s and 1980s through a Federal Maximum Allowable Cost program

that placed ceilings on reimbursement levels for generic drugs. (Reid Decl., Ex. 199, at 32,297-98.)

239. In 1987, the federal government furthered its efforts to allow states to benefit from steep discounts in the generic market by adopting the FUL program expressly for the purpose of encouraging migration to lower-cost generic drugs. (Reid Decl., Ex. 200.)

240. The FUL program was intended to "enable[] the Federal and State governments to take advantage of savings that are . . . available in the marketplace for multiple source drugs" while at the same time maintaining flexibility for states to determine their own reimbursement rates and to experiment with methods of furthering controlling the cost of offering Medicaid beneficiaries a prescription drug benefit. (Reid Decl., Ex. 201.)

241. From 1987 to 2006, the FUL regulation provided that a state's reimbursement for multiple source drugs "in the aggregate" must not exceed 150% of the published price for the least costly therapeutically equivalent product where at least three suppliers market a given generic drug. (Reid Decl., Ex. 202.)

242. CMS instituted FULs for Dey's albuterol unit dose, albuterol multi dose, 90MCG inhaler, and ipratropium bromide NDCs at issue during the time period at issue. (*See* Bradford Decl., Figure 6.)

243. For the states for which Dr. Bradford had state-level claims data, approximately 15.5 percent of claims for the Subject Drugs for which there is claims data in the record are reimbursed on the basis of the FUL. (Bradford Decl., Figure 5.)

244. CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet their dual objectives of cost savings

and access. Despite regulations stating otherwise, CMS based FULs on prices that were not the lowest published prices. (Reid Decl., Ex. 203, at 225:16-226:7; Reid Decl., Ex. 204, at 73:14-74:22; Reid Decl., Ex. 255 at 428:10-20; Reid Decl., Ex. 202.)

245. CMS conducts a manual review of proposed FUL prices to determine whether a drug was "truly available or not" and whether or not "you should follow up and see if it's available." (Reid Decl., Ex. 203, at 229:8-230:14.)

246. This manual review was implemented for the Dey albuterol drugs at issue in this motion. (*See, e.g.*, Reid Decl., Ex. 204, at 89:2-5, 93:12-94:16; Reid Decl., Ex. 205, at 470:2-472:21, 474:7-16, 496:21-497:7.)

247. For example, Susan Gaston, CMS Heath Insurance Specialist, Pharmacy Division, and the person in charge of setting FULs at CMS, testified that CMS removed the FUL for the 90 MCG albuterol inhaler upon learning of a shortage of the drug's raw material because "if the product is not available then it wouldn't make sense to put a FUL price on it." (Reid Decl., Ex. 205, at 470:7-472:21.)

248. The FUL regulation does not establish a reimbursement rate for any drug, but affords the states flexibility in setting reimbursement rates for particular drugs so long as the state reimburses at or below the applicable FUL limitation. (*See* 42 C.F.R § 447.304 (2009); *See* 42 C.F.R § 447.512 (2009); *See* 42 C.F.R § 447.514 (2009); *See* 42 C.F.R § 447.518 (2009).)

249. Dey hereby incorporates Defendants' Motion for Partial Summary Judgment and related filings on issues relating to the FUL in the *City of New York, et. al v. Abbott Laboratories, et. al.*, 01-12257-PBS, Dockets 6052, 6053, and 6054, and the Affidavit of Cesar A. Perales; the Affidavit of Dr. Sumanth Addanki, and the Declaration of Kim B.

Nemirow Transmitting Deposition Testimony and Hearing Transcripts Relied Upon in Support of Defendants' Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims. (Reid Decl., Ex. 206-208, 293-295.)

250. After 2001, in instances where there was a FUL for a drug that was higher than the state MAC, it was Hawaii's practice to reimburse at the higher FUL. This is contrary to Hawaii's State Plan, which provided for reimbursement at "the lower of" billed charges, the provider's usual and customary charge, estimated acquisition cost, FUL or the State MAC. (*See* Reid Decl., Ex. 209, at 174:4-188:14; Reid Decl., Ex. 210, at 4(a)2.)

Providers' Usual and Customary Charges

251. Pharmacy providers must submit the usual and customary charges to states. (*See, e.g.*, Reid Decl., Ex. 192, at 116:4-9; Reid Decl., Ex. 211, at 689:10-13; Reid Decl., Ex. 212, at 70:3-5; Reid Decl., Ex. 142, at 78:16-79:4; Reid Decl., Ex. 198, at 69:17-70:1; Reid Decl., Ex. 213, at 381:15-18; Reid Decl., Ex. 214, at 142:16-143:10; Reid Decl., Ex. 215, at 108:7-12; Reid Decl., Ex. 195, at 220:1-7; Reid Decl., Ex. 216, at 55:21-56:3; Reid Decl., Ex. 145, at 96:7-14; Reid Decl., Ex. 217, at 133:12-14; Reid Decl., Ex. 218, at 108:15-109:3; Reid Decl., Ex. 219, at 237:11-15; Reid Decl., Ex. 220, at 145:19-146:12; Reid Decl., Ex. 146, at 427:19-22; Reid Decl., Ex. 221, at 147:15-22; Reid Decl., Ex. 196, at 61:2-3; Reid Decl., Ex. 222, at 183:2-5, 185:17-20; Reid Decl., Ex. 223, at 228:10-20; Reid Decl., Ex. 224, at 86:4-16; Reid Decl., Ex. 225, at 53:7-10; Reid Decl., Ex. 148, at 299:16-19; Reid Decl., Ex. 149, at 67:11-17; Reid Decl., Ex. 150, at 255:14-15; Reid Decl., Ex. 226, at 309:19-310:1; Reid Decl., Ex. 227, at 246:10-14.)

252. While usual and customary charges are always submitted by providers, there is variation amongst states' definitions of usual and customary. For example, Alabama Medicaid's provider manual defines "usual and customary charges" as an "[a]mount which a provider usually and most frequently charges patients for a specific service in normal medical circumstances." (Reid Decl., Ex. 228.)

253. The Virginia Department of Medical Assistance Services' provider manual, appendix A, defines "customary charge" as "[t]he amount providers usually bill patients for furnishing particular services or supplies." (Reid Decl., Ex. 229.)

254. Massachusetts defines "usual and customary charge" as "the lowest price that a pharmacy charges or accepts from any payer for the same quantity of a drug on the same date of service, in Massachusetts, including but not limited to the shelf price, sale price, or advertised price of an over-the-counter drug." (*See* 130 Mass. Code Regs. 406.402 (2009).)

255. Pharmacy providers must verify/certify that the usual and customary charges they submit are accurate. (*See, e.g.*, Reid Decl., Ex. 212, at 74:3-6; Reid Decl., Ex. 198, at 158:10-159:5; Reid Decl., Ex. 214, at 120:11-14, 125:11-127:15; Reid Decl., Ex. 217, at 53:18-54:6; Reid Decl., Ex. 218, at 318:8-11; Reid Decl., Ex. 220, at 66:20-67:10; Reid Decl., Ex. 146, at 210:9-13; Reid Decl., Ex. 224, at 87:9-88:6; Reid Decl., Ex. 149, at 80:7-18; Reid Decl., Ex. 150, at 258:4-259:2, 268:3-8.)

256. The Government has not contended that the usual and customary charge submitted by the providers are in any way fraudulent. (Reid Decl., Ex. 230.)

257. Reimbursements are made at the pharmacists' usual and customary charge if it is lower than the other available reimbursement benchmarks, including Dey's published WAC and AWP. (*See* 42 C.F.R. § 447.512(b) (2009).)

258. For the states for which Dr. Bradford had state-level claims data, approximately, 10.2 percent of claims for the Subject Drugs for which there is claims data in the record are reimbursed on the basis of the provider's usual and customary charge. (Bradford Decl., Figure 5.)

Dispensing Fees

259. Each state also includes a state-specific dispensing fee in their reimbursement methodology. (*See* 42 C.F.R § 447.512 (2009); *See* 42 C.F.R § 447.514 (2009).)

260. Dispensing fees differ by state. (Reid Decl., Ex. 33, at 586:10-21.)

The DOJ Revised AWPs

261. The revised AWPs for Dey's albuterol and cromolyn were also circulated to state Medicaid agencies. (Reid Decl., Ex. 231; Reid Decl., Ex. 232.)

262. The DOJ AWPs were rejected by many states, in whole or in part. (Reid Decl., Ex. 233; Reid Decl., Ex. 232, at ii.) However, at least 18 states chose not to use these lower prices that were recommended and made available to them. Even among the 30 states that actually used these lower revised-AWPs for reimbursement purposes, many expressed skepticism that they will lead to any long-term savings. (Reid Decl., Ex. 232, at ii.)

263. Cody Wiberg, former pharmacy program manager for Minnesota Medicaid, sent an e-mail to a listserve for National Medicaid Pharmacy Administrators on June 22, 2000 relating to the revised AWPs proposed by NAMFCU in which he stated: "Almost

everyone who is familiar with pharmacy reimbursement knows that AWP "Ain't What's Paid". That's why most states and private pharmacy benefit managers reimburse pharmacies at AWP minus a discount (anywhere from 5-15% or more). It is also one reason why there is a federal upper limit list and why many states and private PBMs have maximum allowable cost programs. The spread between AAC and AWP is taken into account when determining what to pay for a dispensing fee." (Reid Decl., Ex. 233, at 2.)

264. Mr. Wiberg's e-mail continued: "Some public and private third part payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquisition cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation." (Reid Decl., Ex. 233, at 2.)

C. BECAUSE DIFFERENT STATES MAKE DIFFERENT CHOICES, NO TWO MEDICAID PROGRAMS ARE THE SAME

265. Dey only reports one set of prices for publication nationwide yet states have separate and vastly different payment rates for Dey's Subject Drugs. (Stiroh Figures A-K; Reid Decl., Ex. 35, at 433:8-449:12).

266. Harry Leo Sullivan, the former Pharmacy Director of the Tennessee Medicaid program, testified that he and other states knew that AWP was not an actual acquisition cost:

Q. During the entirety of the time that you were the director of pharmacy services for Tennessee Medicaid, did you believe that the AWPs in the compendia were a reliable source of information regarding what pharmacies or physicians actually paid for drugs?

A. No.

Q. And from your interactions with other state pharmacy administrators, in your view did other state pharmacy administrators believe that AWPs were a reliable source for what pharmacies and physicians actually paid for drugs?

MR. DRAYCOTT: Objection.

A. Again, I don't ever remember such a specific discussion with, with those peers, because it just wouldn't come up. I – everybody knows the sky's blue. I mean it is that basic to me. I couldn't imagine some -- one of your peers in that situation sitting down and saying, Hey, Did you know pharmacists really aren't paying AWP?

Q. So just as the sky, just as everyone knows the sky is blue, you think your peers knew that average wholesale prices did not represent a reliable source of the prices at which physicians and pharmacies actually paid for drugs.

A. That's correct.

(Reid Decl., Ex. 148, at 98:4-99:9.)

267. Ingredient reimbursement formulas vary from state to state, and have varied over time within states. As stated by Mr. Scully, "[d]ifferent states had different purchasing arrangements, obviously different dispensing fees, different mixes…different prices…different formularies." (Reid Decl., Ex. 33, at 586:10-18.)

268. Cody Wiberg, former Pharmacy Program Manager for Minnesota's Medicaid program, testified to the diversity of state Medicaid programs: "one of the things you have to understand is, in addition to AWP being 'ain't what's paid,' another common saying that we have was if you've seen one Medicaid Pharmacy Program, you've seen one Medicaid Pharmacy Program." (Reid Decl., Ex. 196, at 199:5-10.)

269. As seen in the charts attached to the Bradford Declaration, the choices made by states result in a variety of payments based on a variety of bases. (*See* Bradford Decl., Figures 4, 5, 49).

270. Because of this flexibility, each state Medicaid program is able to weigh various unique local considerations and, as a result, often make different choices when deciding on prescription drug reimbursement rates. (Reid Decl., Ex. 234, at 78:3-22, 136:11-137:8, 156:18-158:6, 161:18-162:8, 163:14-164:4; Reid Decl., Ex. 235, at 763:10-764:11; Reid Decl., Ex. 217, at 34:15-35:4, 38:4-39:16; Reid Decl., Ex. 192, at 140:13-141:1; Reid Decl., Ex. 146, at 142:5-143:10.)

271. The reimbursement rates each state Medicaid program selects are the result of deliberate policy choices among these components driven by negotiations with or legal action from pharmacy groups, complying with legislative mandates, and ensuring Medicaid recipients have access to services by providing sufficient spread between a provider's acquisition cost and whatever formula a state chooses so that providers remain in the program. (*See, e.g.*, Reid Decl., Ex. 226, at 99:9-100:7, 38:3-9, 40:20-41:5, 196:4-17, 202:4-10, 224:18-225:14; Reid Decl., Ex. 196, at 50:10-18, 111:5-14, 136:7-22, 171:9-172:18; Reid Decl., Ex. 217, at 38:4-41:4, 121:2-122:3, 122:14-124:12; Reid Decl., Ex. 192, at 51:4-52:21, 226:4-14; Reid Decl., Ex. 236,

at 64:10-65:30, 145:3-146:17; Reid Decl., Ex. 237, at 124:7-125:6; Reid Decl., Ex. 238, at 188:18-189:9, 190:22-191:11; Reid Decl., Ex. 239, at 228:16-234:21; Reid Decl., Ex. 240, at 351:15-353:2; Reid Decl., Ex. 241, at 175:6-176:25; Reid Decl., Ex. 242, at 186:9-187:2, 190:21-25, 224:4-15; Reid Decl., Ex. 234, at 169:8-22; Reid Decl., Ex. 146, at 51:8-53:14; Reid Decl., Ex. 148, at 167:16-170:2; Reid Decl., Ex. 142, at 150:17-153:17; Reid Decl., Ex. 198, at 136:12-137:2, 138:8-140:2, 148:10-150:12, 257:3-21.)

272. States do not always follow the formulas they have adopted. (Bradford Decl., Figure 5.)

273. State Medicaid programs have generally reimbursed for the ingredient cost of each drug based on the lowest of the EAC as set by the states, the MAC set by the state, the FUL, or the providers' usual and customary charge, or other state-specific bases. (Reid Decl., Ex. 226, at 77:11-16; Reid Decl., Ex. 243; Reid Decl., Ex. 192, at 31;14-18, 37:2-21; Reid Decl., Ex. 244; Reid Decl., Ex. 245.)

274. For those states that base EAC on AWP, EAC is calculated as AWP less a percentage. (Reid Decl., Ex. 226, at 279:9-13, 72:19-73:4, 77:17-20; Reid Decl., Ex. 246, at WA-00001282; Reid Decl., Ex. 243; Reid Decl., Ex. 247; Reid Decl., Ex. 248; Reid Decl., Ex. 192, at 31:14-18, 37:2-21; Reid Decl., Ex. 249; Reid Decl., Ex. 234, at 169:4-7, 333:17-334:1, 385:7-11; Reid Decl., Ex. 250; Reid Decl., Ex. 251.)

275. Forty-one states require generic substitution because it is generally cheaper than the brand. (Reid Decl., Ex. 196, at 257:12-258:7; Reid Decl., Ex. 217, at 72:3-22, 73:6-12, 74:1-21, 155:15-156:13, 157:3-7; Reid Decl., Ex. 192, at 67:10-68:3; Reid Decl., Ex. 252, at 571:22-573:7; Reid Decl., Ex. 238, at 134:8-135:10, 142:10-15; Reid Decl., Ex. 239, at

112:5-13; Reid Decl., Ex. 234, at 93:2-13; Reid Decl., Ex. 148, at 60:12-61:14, 62:13-63:10; Reid Decl., Ex. 253, at 2.)

276. Most states have chosen to calculate EAC based on a discount from AWP, but some have relied on WAC pricing data. (*See, e.g.*, Reid Decl., Ex. 245; Reid Decl., Ex. 270, at 604:11-21; Reid Decl., Ex. 238, at 34:15-35:1.)

277. Still others have used one benchmark only to switch to another benchmark at a different point in time, such as Florida (WAC pricing to AWP-based reimbursement and back to WAC). (Reid Decl., Ex. 245; Reid Decl., Ex. 254; Reid Decl., Ex. 255.)

278. Furthermore, some states have frequently revised the discount on AWP or the percentage added to WAC and others have chosen not to revise the calculation or modify it only rarely. Alaska has maintained its EAC at AWP-5% since 1990, and Minnesota has modified its EAC formula four different times in the span of about ten years, from AWP-10%, AWP-14%, AWP-11.5% and then to AWP-12%. (Reid Decl., Ex. 234, at 169:4-7, 333:17-334:1, 385:7-11; Reid Decl., Ex. 243; Reid Decl., Ex. 256; Reid Decl., Ex. 257; Reid Decl., Ex. 196, at 130:9-131:10.)

279. States routinely impose MACs or rely on FULs for particular drugs as a way to control costs, and Dey's Subject Drugs were frequently subject to such caps. (Reid Decl., Ex. 211, at 505:1-17; Reid Decl., Ex. 258, at 352:24-353:2; Reid Decl., Ex. 146, at 47:18-22, 151:2-10; Reid Decl., Ex. 142, at 99:16-102:12.)

280. Some states, including Georgia and New Hampshire, establish MAC prices based on a proprietary formula by a contractor. (Reid Decl., Ex. 259, at 66:11-67:10; Reid Decl., Ex. 198, at 207:3-209:2.)

281. Other states, including Arkansas, Tennessee, and Washington surveyed providers about their invoice or actual acquisition costs. (Reid Decl., Ex. 148, at 106:18-109:19; Reid Decl., Ex. 192, at 65:3-11, 244:14-246:1; Reid Decl., Ex. 226, at 265:12-266:9, 238:17-22; Reid Decl., Ex. 260, at 37:12-38:11, 59:16-20.)

282. States did surveys, set MACs, and received Dey's letters regarding Dey's WAC and AWP. (Reid Decl., Ex. 226, at 105:9-107:13, 135:3-10, 211:21-212:6; Reid Decl., Ex. 261; Reid Decl., Ex. 262; Reid Decl., Ex. 196, at 246:5-247:2; Reid Decl., Ex. 263; Reid Decl., Ex. 217, at 148:8-149:18; Reid Decl., Ex. 238, at 145:22-146:14; Reid Decl., Ex. 193, at 204:16-20; Reid Decl., Ex. 264, at 74:16-19, 76:3-11; Reid Decl., Ex. 234, at 168:1-169:2; Reid Decl., Ex. 265, at 355:15-357:5; Reid Decl., Ex. 146, at 331:5-21; Reid Decl., Ex. 142, at 218:4-219:21; Reid Decl., Ex. 198, at 268:15-271:19.)

283. States regularly met with each other and shared information. (Reid Decl., Ex. 260, at 72:1-19, 97:8-21; Reid Decl., Ex. 196, at 148:5-152:16; Reid Decl., Ex. 259, at 60:22-61:19; Reid Decl., Ex. 266, at 857:25-859:9; Reid Decl., Ex. 267, at 735:5-19, 736:20-23; Reid Decl., Ex. 235, at 529:20-531:2.)

284. Delaware's 30(b)(6) designee, Cynthia Denemark, testified that Delaware has understood since at least 1993 that AWP does not reflect a providers' actual acquisition cost, but nonetheless Delaware continues to rely on AWP as one possible basis for reimbursement in order to cross-subsidize Delaware's inadequate dispensing fee. (*See* Reid Decl., Ex. 142, at 268:1-269:3.)

VII. DATA UTILIZED IN ANALYSES

285. Plaintiffs' damages expert, Dr. Mark Duggan, submitted an expert report in this case which analyzed claims data for 14 states. However, even for those states, he is not solely relying on detailed claims data to calculate differences. (Reid Decl., Ex. 270; Bradford Decl. ¶ 28.)

286. Claims data was available for 32 states. (Bradford Decl. ¶ 25.)

287. SDUD is aggregate data containing the state, the NDC, the name of the drug, the total units reimbursed for that quarter, the total number of prescriptions for the quarter, the total amount reimbursed for that NDC for the quarter, and quarter covered. (Reid Decl., Ex. 268; Bradford Decl. ¶ 26.)

288. MAX/SMRF data has some claims-level data, but it is not available for all states prior to 1999, and does not include quantity for any state prior to 1996. (Reid Decl., Ex. 269; Bradford Decl. ¶ 27.)

289. MAX/SMRF also does not include dispensing fee and co-payments, which reduces the precision of attempts to calculate the reimbursement basis. (Bradford Decl. ¶ 27.)

290. MAX/SMRF data is also rounded, which further reduces the precision of payment basis analysis. (Bradford Decl. ¶ 27.)

291. Pricing arrays have not been produced for all DMERCs-quarters at issue. Dr. Duggan has extrapolated his 'difference' calculations for quarters with missing pricing arrays. There are many idiosyncratic variations in pricing array across DMERCs and over quarters, thus making a straightforward extrapolation problematic. (Bradford Decl., ¶¶ 34, 35.) Furthermore, Dr. Duggan calculates differences for some arrays where the DMERCs did not include Dey's NDCs. (Bradford Decl., ¶¶ 34, 35.)

292. Dr. Duggan testified that his basis for creating joint "differences" scenarios for Dey and Roxane is that both had been sued by the Government. (Reid Decl., Ex. 291 at 434:1-7).

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Respectfully Submitted,

KELLEY DRYE & WARREN LLP

By: /s/Sarah L. Reid

Paul F. Doyle (BBO # 133460)
Sarah L. Reid *(pro hac vice)*
William A. Escobar *(pro hac vice)*
Neil Merkl *(pro hac vice)*
101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Attorneys for Defendants Dey, Inc. Dey, L.P., and Dey, L.P., Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on June 26, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid